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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/550,419 | 05/30/2007 | Thomas Pittelkow | 05432/100M680-US1 | 3350 |

7278 7590 06/02/2009
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| EXAMINER |
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CHANDRAKUMAR, NIZAL S

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| ART UNIT | PAPER NUMBER |
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1625

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| MAIL DATE | DELIVERY MODE |
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06/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,419

Applicant(s)

PITTELKOW ET AL.

Examiner

NIZAL S. CHANDRAKUMAR

Art Unit

1625

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 12, 21, 23, 25, 28, 33, 36, 39, 42, 46, 48-50 and 57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 50 and 57 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 12, 21, 23, 25, 28, 33, 36, 39, 42, 46, 48 and 49 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/09/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

This application is a 371 of PCT/DK04/00177 03/17/2004
which claims benefit of 60/456,415 03/21/2003.

Claims 1-4, 12, 21, 23, 25, 28, 33, 36, 39, 42, 46, 48, 49, 50 and 57 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, Line 8: In the definition of X and Y of formula VIIA, the meaning of NR is unclear as this definition accommodates only two of three valencies of nitrogen; as such the scope of the substituents on the nitrogen is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 57 is rejected under 35 U.S.C. 102(b) as being anticipated by Petersen et al. WO 0039112.

Petersen et al. teach (page 5, line 26) compound of formula (III) wherein R3 is C2 alkyl.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 50 rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al. WO 0039112.

Petersen et al teach the preparation and isolation of compound corresponding to compound of formula (III) wherein R3 is a C2- alkyl by using a C2 alcohol (ethanol) on page 5, line 26-30 of '112. (Petersen et al. teaches the conversion of this C2-compound to primary amide in page 6, of '112, en route to commercially important citalopram. One skilled in the art would anticipate this conversion to be independent of the nature of the alkyl group R3 of instant formula (III). Instant claim 46 which depends on claim 1, is drawn to amide disclosed by Petersen et al.)

Petersen et al do not teach the preparation of compound of formula (III) wherein R3 is a C3-C6- alkyl.

Preparation and isolation of C3-C6 alkyl esters by extension of the procedures of Petersen et al. by choosing C3-C6 alcohols over C2-alcohol is well within one of skilled in the art. Adjacent alkyl homologs are obvious variants. It would have been obvious to one of ordinary skill in the art to modify an otherwise known process to obtain functionally (see above) equivalent variants using homologous alcohols as the results would not have been unexpected.

Allowable Subject Matter

The subject matter of claims 2-4, 12, 21, 23, 25, 28, 33, 36, 39, 42, 46, 48, and 49 is deemed allowable. The claims as instantly presented are objected to for depending on rejected base claim 1. The process of making carboxyphthalide by reaction of terephthalic acid with oleum and formaldehyde (or its equivalent) is known in the prior art See Abstract of US 6403813. The instant claims are drawn to a process of making 5-alkoxycarbonylphthalide, in which the esterification to introduce the alkoxy group is performed in situ. Enabling disclosure is found for introduction of alkoxy group (esterification) by addition of the reaction mixture of step a) to alcohol (that is inverse addition). As such, amendments to claim 1 commensurate with this manner of process step b), without introducing new matter, would be required to place these claims in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nizal S Chandrakumar/
Examiner, Art Unit 1625